

### REMARKS

Claims 5 and 7-95 are pending herein. By this Amendment, Claims 1-4 and 6 are canceled, without prejudice or disclaimer; Claims 5, 7, 9-11, 15, 17-20, 22-23, and 25-29 are amended; and new Claims 83-95 are added. Support for the claim amendments and new claims is found in the specification at, *inter alia*, page 6, last 2 lines; page 8, lines 13-22; page 10, lines 12-34; page 11, lines 3-6 and 14-21; page 16, lines 1-2; and in the original claims. No new matter is added by this Amendment.

#### I. RESTRICTION REQUIREMENT

Claims 1-30 were elected with traverse in the Response to Restriction Requirement filed October 26, 2001. For the reasons set forth in that Response, Applicants respectfully maintain that unity of invention exists among Groups I-III and request that Claims 31-82 also be examined.

#### II. FORMAL MATTERS

Claims 3, 5, 7, 9-11, 15, and 18-20 were objected to on formal grounds. Claim 3 is canceled. Claims 5, 7, 9-11, 15, and 18-20 are amended to correct spelling and punctuation errors. Reconsideration and withdrawal of the objection are respectfully requested.

Claims 1-2 and 6-30 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite. Claims 1-2 and 6 are canceled. This rejection is variously obviated and traversed with respect to Claims 7-30.

Examples of the claimed long chain fatty acids recited in Claims 7, 19, 22, and new Claim 83 are identified in the specification as: (1) docosaheanoic acid;

(2) docosapentaenoic acid; and (3) eicosapentaenoic acid. Further, the fact that claim language includes relative terms or terms of degree does not automatically render the claim indefinite. See MPEP 2173.05(b). As the specification provides guidance to the meaning of "long chain" fatty acids and this term is well known to one of ordinary skill in the food art, the pending claims are not indefinite.

The term "crude" distinguishes a raw ingredient from a "refined" ingredient and would be readily understood by one of ordinary skill in the art. In fact, the term "crude" is defined in *The American Heritage Dictionary* as "in an unrefined or natural state; raw." The 81% after phosphoric acid refers to the potency. Thus, 81% of the ingredient used is pure phosphoric acid. China Star indicates the highest quality aniseed and this grade identification is well known to one of ordinary skill in the art. The term "Vitamin E 50" is also well known to those of ordinary skill in the food art as indicating a potency of 50% (i.e., 500 mg pure Vitamin E). Regarding Claim 27, "aqueous extraction" refers to extraction with or by water.

The scope of the pending claims would be reasonably ascertainable to one of ordinary skill in the art when read in light of the specification, thereby satisfying the requirements of 35 U.S.C. 112, second paragraph. Reconsideration and withdrawal of the rejection are respectfully requested.

### III. REJECTIONS UNDER 35 U.S.C. 102(b)

Claims 1-5 were rejected under 35 U.S.C. 102(b) over O'Keefe et al. (Food Research International (1995), vol. 28, no.4, pp. 417-24). Claims 1-4 are canceled. The rejection is respectfully traversed with respect to Claim 5.

O'Keefe discloses feeding broiler chickens a diet supplemented with 0, 4, 8, and 12% fish meal. According to the analysis performed by O'Keefe, "[u]nder the dietary conditions examined oxidation during refrigerated storage of cooked chicken appears to limit the amount of fish meal supplementation possible to 4%" (Emphasis added). See Abstract and page 422, left column, last paragraph. Thus, levels of fish meal higher than 4% are a cause of taint and oxidative instability in the meat. O'Keefe does not disclose an animal feed supplement comprising fish meal as a source of omega 3 long chain fatty acids, wherein the omega 3 long chain fatty acids are increased to a level which maximizes the nutritional value of food produce from the animal by increased level of long chain omega 3 fatty acids but without taint of the produce. Further, O'Keefe does not teach that the feed supplement is greater than 5% of the total dietary intake of the animal. Accordingly, O'Keefe does not disclose each and every element of the claimed feed supplement and does not anticipate Claim 5. Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 1-5 were rejected under 35 U.S.C. 102(b) over Howe (World Review of Nutrition and Dietetics (1998), vol. 83, pp. 132-143). Claims 1-4 are canceled. The rejection is respectfully traversed with respect to Claim 5.

Howe discloses that in order to ensure optimal shelf life of frozen pork, it is suggested that the fish meal content of feed rations be limited to 2% when fed or 5% if withdrawn 5-7 weeks before slaughter (page 136, last paragraph). Howe also discloses a pilot program in which pigs were fed a diet containing 20% of a high-grade fish meal formulation (page 137). Howe states that "after frozen storage, however, there was a clear preference for cooked meat from the control pigs", i.e., those pigs fed without fish meal (page 138). Thus, Howe does not

disclose an animal feed supplement comprising fish meal as a source of omega 3 long chain fatty acids, wherein the omega 3 long chain fatty acids are increased to a level which maximizes the nutritional value of food produce from the animal by increased level of long chain omega 3 fatty acids but without taint of the produce. Further, Howe does not teach that a fishmeal feed supplement is greater than 5% of the total dietary intake of the animal. Accordingly, Howe does not disclose each and every element of the claimed feed supplement and does not anticipate Claim 5. Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 1-5 were rejected under 35 U.S.C. 102(b) over Mandell et al. (World Review of Nutrition and Dietetics (1998), vol. 83, pp. 144-59). Claims 1-4 are canceled. The rejection is respectfully traversed with respect to Claim 5.

Mandell discloses a diet for cattle that contains up to 10% fish meal. Mandell discloses that the use of fish meal to enrich the omega-3 fatty acid content of beef was accompanied by fish taint (page 154, last paragraph). Mandell does not disclose an animal feed supplement comprising fish meal as a source of omega 3 long chain fatty acids, wherein the omega 3 long chain fatty acids are increased to a level which maximizes the nutritional value of food produce from the animal by increased level of long chain omega 3 fatty acids but without taint of the produce and wherein the feed supplement is greater than 5% of the total dietary intake of the animal. Thus, Mandell does not disclose each and every element of the claimed feed supplement and does not anticipate Claim 5. Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 1-5 were rejected under 35 U.S.C. 102(b) over German Patent No. 43 27 310 A1. Claims 1-4 are canceled. The rejection is respectfully traversed with respect to Claim 5.

DE '310 discloses a feed additive composition for cows that contains 30-60% of a fatty acid source, such as linseed and perilla seed and optionally 5-10% fish meal (i.e., the percentage of fish meal in the additive composition is at most 6%). The objective of DE '310 is to obtain milk containing fatty acids. As noted from Mandell, the corresponding beef of DE '310 would be expected to have taint due to the use of fish meal. DE '310 does not disclose an animal feed supplement comprising fish meal, wherein omega 3 long chain fatty acids are increased to a level which maximizes the nutritional value of food produce from the animal by increased level of long chain omega 3 fatty acids but without taint of the produce; wherein the produce is pork, poultry meat, lamb, eggs, beef or farmed fish; and wherein the feed supplement is greater than 5% of the total dietary intake of the animal. DE '310 does not disclose each and every element of the claimed animal feed supplement and does not anticipate Claim 5. Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 1-5 were rejected under 35 U.S.C. 102(b) over U.S. Patent No. 5,133,963 (Ise). Claims 1-4 are canceled. The rejection is respectfully traversed with respect to Claim 5.

Ise discloses a method of increasing the concentration of omega-3 fatty acids in poultry products. Ise discloses feeding a supplement containing 8% fish meal to poultry (col. 7, line 29). However, Ise states that fish meal, unless subjected to a vacuum deodorizing process, is not suitable as a poultry feed additive because an unpleasant odor is transferred to the meat and eggs (col. 5,

lines 44-46). Ise does not disclose an animal feed supplement comprising fish meal, wherein omega 3 long chain fatty acids are increased to a level which maximizes the nutritional value of food produce from the animal by increased level of long chain omega 3 fatty acids but without taint of the produce and wherein the feed supplement is greater than 5% of the total dietary intake of the animal. Thus, Ise does not disclose each and every element of the claimed feed supplement and does not anticipate Claim 5. Reconsideration and withdrawal of the rejection are respectfully requested.

#### IV. REJECTION UNDER 35 U.S.C. 103(a)

Claims 6-30 were rejected under 35 U.S.C. 103(a) over O'Keefe or Howe or Mandell in view of Japanese Patent No. 06209720 A; Roubal (Journal of the American Chemists' Society (1963) vol. 40, pp.215-18); U.S. Patent No. 5,130,242 (Barclay); U.S. Patent No. 5,972,391 (Suzuki et al.); and U.S. Patent No. 5,112,624 (Johna et al.). Claim 6 is canceled. The rejection is respectfully traversed with respect to Claims 7-30.

As noted above, O'Keefe, Howe, and Mandell ("primary references") do not disclose an animal feed supplement comprising fish meal, wherein omega 3 long chain fatty acids are increased to a level that maximizes the nutritional value of food produce from the animal by increased level of long chain omega 3 fatty acids but without taint of the produce, and wherein the feed supplement is within the range of 5%-20% of the animal's total diet, as recited in Claim 22. Further, none of the primary references teaches or suggests an animal feed supplement comprising a water based green tea extract, as recited in Claims 7-16. In addition, none of the primary references teaches or suggests an animal feed supplement

comprising tuna meal and the combination of ingredients recited in Claim 17-21 and 23-30.

A. JP '720

JP '720 does not overcome the deficiencies of the primary references. JP '720 discloses obtaining a meat having high commercial value by feeding a domestic animal with a feed containing tannin, caffeine, etc. such as green tea, black tea and coffee beans. The meat quality and color can be improved and the meat may be able to stimulate the nerves and raise blood pressure due to the caffeine and inhibit absorption of fat and suppress cholesterol due to the tannin.

There is no teaching or suggestion in JP '720 to make an animal feed supplement with the combination of fish meal and a water-based green tea extract in order to maximize the level of omega 3 fatty acids without producing taint.

It is axiomatic that the teachings of references can be combined only if there is some suggestion to do so. The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification. Further, as noted in *In re Lee*, 61 USPQ2d 1430 (Fed. Cir. 2002), there is a need for factual specificity and thoroughness underlying any inquiry regarding the combination of references and such inquiry cannot "be resolved on subjective belief and unknown authority." This factual showing is essential to avoid the use of improper hindsight and the use of an inventor's own teachings against him.

The primary references and JP '720 give no indication that the combination of fish meal and green tea extract is desirable in an animal feed supplement, particularly for the purpose of maximizing the amount of omega-3 fatty acids in

the food produce of an animal without producing taint. In fact, the problems addressed in JP '720 (blood pressure, fat absorption, and cholesterol suppression) are unrelated to the problems addressed by the primary references of adding omega 3 fatty acids to animal food produce. Thus, it would not have been obvious for one of ordinary skill in the art to make the claimed feed supplements or practice the claimed methods of Claims 7-16 in view of combined teachings of the primary references and JP '720.

B. Roubal

Roubal does not overcome the deficiencies of the primary references. Roubal discloses that tuna oil comprises polyunsaturated fatty acids.

Like the primary references, Roubal does not teach or suggest an animal feed supplement comprising fish meal as a source of omega 3 long chain fatty acids, wherein the omega 3 long chain fatty acids are increased to a level that maximizes the nutritional value of food produce from the animal by increased level of long chain omega 3 fatty acids but without taint of the produce and wherein the feed supplement is within the range of 5%-20% of the animal's total diet. Further, the primary references and Roubal do not teach or suggest an animal feed supplement containing additional claimed constituents, for example, ethoxyquin, Vitamin C, citric acid, propyl gallate, wheat meal, and green tea extract. Thus, it would not have been obvious for one of ordinary skill in the art to make the claimed feed supplements or practice the claimed methods of Claims 7-30 in view of combined teachings of the primary references and Roubal.



C. Barclay

Barclay does not overcome the deficiencies of the primary references. Barclay discloses a process for the production of whole-celled or extracted microbial products with a high concentration of omega-3 highly unsaturated fatty acids. Barclay discloses adding antioxidants such as Vitamin E and Vitamin C to the microbial products (cols. 10-11). However, Barclay *teaches away* from fish-based food supplements:

There are significant problems with the use of fish oil as a feed additive or supplement. First and most significantly, fish oil has a strong and fishy taste and odor and as such cannot be added to processed foods as a food additive, without negatively affecting the taste of the food product. This is also true for many of its applications as an animal food or feed additive....

As a result ... there is an important need for the development of **alternative (non-fish based) sources of omega-3 HUFAs**.

(col. 16, line 32- col. 12, line 12, emphasis added). Thus, there is no teaching or suggestion in Barclay to add antioxidants to an animal food supplement containing fish meal. Rather, one of ordinary skill in the art would have been led away from animal food supplements containing fish meal to animal food supplements containing microbial products as a source of omega 3 fatty acids. Similarly, there is no teaching or suggestion to use ethoxyquin, benzoic acid, and propyl gallate as antioxidants in a feed supplement containing fish meal in view of Barclay. Barclay also does not teach or suggest a feed supplement comprising a water based green tea extract. Thus, it would not have been obvious for one of ordinary skill in the art to make the claimed feed supplements or practice the claimed methods of Claims 7-30 in view of combined teachings of the primary references and Barclay.

Pursuant to MPEP 2144.03, Applicants respectfully request the Examiner to cite a reference in support of the assertion that animal diets require a fat source including palm oil and canola oil.

D. Suzuki et al.

Suzuki et al. does not overcome the deficiencies of the primary references. Suzuki et al. discloses a swine feed containing additives such as aniseed, thyme, rosemary, as well as Vitamin E (col. 2).

Like Roubal and Barclay, Suzuki et al. does not teach or suggest a feed supplement comprising fish meal and (1) a green tea extract, or (2) one or more of Vitamin C, citric acid, propyl gallate, benzoic acid, phosphoric acid, calcium propionate and wheat meal, in order to maximize the level of omega 3 fatty acids without producing taint. Thus, it would not have been obvious for one of ordinary skill in the art to make the claimed feed supplements or practice the claimed methods of Claims 7-30 in view of combined teachings of the primary references and Suzuki et al.

E. Johna et al.

Johna et al. does not overcome the deficiencies of the primary references. Johna et al. discloses a method for preventing digestive disturbances in herbivores by supplementing their feed with pancreatin. To mask the taste of the pancreatin, a peppermint flavoring may be added (col. 2, lines 25-42).

The primary references do not disclose feed supplements containing pancreatin. Moreover, Johna et al. does not disclose a feed supplement containing fish meal. There is no reason why one of ordinary skill in the art would look to the

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teachings of Johna et al. to modify animal feed supplements containing fish meal as a source of omega-3 fatty acids. The Federal Circuit has stated that claims cannot be "used as a frame in which individual, naked parts of separate prior art references [are] employed as a mosaic to recreate a facsimile of the invention." W.L. Gore & Assoc., Inc. v. Garlock, 220 USPQ 303, 312 (Fed. Cir. 1983). By hindsight reconstruction and using the claimed animal feed supplement as a template, the Examiner has recreated the present invention by piecing together the fish meal supplements of the primary references and the unrelated peppermint flavoring of the pancreatin composition of Johna et al.

For the above reasons, it would not have been obvious for one of ordinary skill in the art to make the claimed feed supplements or practice the claimed methods of Claims 7-30 in view of combined teachings of the primary references and Barclay et al., Suzuki et al., and Johna et al. Contrary to the assertion in the Office Action, the combination of cited references do not teach "adding all the ingredient[s] together". Reconsideration and withdrawal of the rejection are respectfully requested.

## V. CONCLUSION

In light of the foregoing remarks, this application should be in condition for allowance, and early passage of this case to issue is respectfully requested. If there are any questions regarding this Amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application.

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Enclosed is a check for \$81.00 to cover the additional claim fee. If any additional fees are due, please charge our Deposit Account No. 501032 (Docket No. WAL5-102).

Respectfully submitted,



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Enclosure: Check for \$81.00

CERTIFICATE OF MAILING

I hereby certify that this correspondence dated 12/17/03 is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on 12/17/03.



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